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Via Electronic Submission

November 6, 2015

Karen B. DeSalvo, MD, MPH, M.Sc.
Office of the National Coordinator for Health IT
200 Independence Ave. SW
Suite 729-D
Washington, DC 20201

Re: 2016 Interoperability Standards Advisory

Dear National Coordinator DeSalvo:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the 2016 Interoperability Standards Advisory. ASCO is the national organization that represents over 35,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans.

The rapid progress in the development and implementation of electronic health records (EHRs) and health information technology (health IT) presents exciting opportunities to improve the health care of millions of Americans. Health IT has the potential to allow oncology providers to quickly and efficiently access treatment information, plan cancer treatments and view a patient's health and treatment history in a comprehensive manner. This is especially important to cancer patients, as their care is usually a collaboration of providers and caregivers that may be spread across healthcare systems, time zones and geographies. Health IT also has the potential to provide medical specialty specific tools and educational links to knowledge bases that are not provided by existing EHRs. Using third party public Application Programming Interfaces (API) and Substitutable Medical Apps, Reusable Technologies (SMART) on Fast Healthcare Interoperability Resources (FHIR) resources with open EHRs will fundamentally enhance our electronic workflows and permit all participating EHRs to have these APIs provide constantly updated specialty-specific information and electronic functionalities that are written once and can run anywhere. For cancer and the other medical specialties this will permit us to provide real-time precision medicine, evidence-based medicine, real-time registry reporting, patient-generated data, patient-sent data that is care-coordinated and value-based that will fundamentally change for the better our interaction with EHRs. For ASCO, another promising application of health IT, is our initiative to build a rapid learning system called CancerLinQ, which has the goal to discover meaningful information to improve clinical care by analyzing longitudinal data from large groups of cancer patients. Thus, interoperability standards (which is the

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571-483-1300
F: 571-366-9530
www.asco.org

pathway towards collecting, sharing and harnessing clinical data) will become a pivotal component of modern cancer care and prevention.

Despite the clear benefits of the seamless exchange of electronic data, our members still face barriers in achieving basic interoperability and bringing about the unburdened exchange of health information. Many existing interoperability standards are designed for primary care and do not meet the needs of specialty care. Without robust interoperability between health IT systems that enables the exchange of treatment information, the nation's health care system risks being unable to effectively leverage the exciting potential of health IT and big data to improve and transform the quality and coordination of care.

ASCO supports the use and development of interoperability standards for the exchange of health information and has engaged in a multi-year initiative to develop standards for the electronic sharing of cancer care information. The problems in achieving widespread interoperability have been well documented. Our members have encountered operational delays, poor system performance, high vendor fees (which in many cases are not only burdensome but pose a barrier to, or at least impede and delay, adoption of health IT) and disruptions partially due to efforts by vendors to comply with the standards for certification of health IT for use in Medicare's meaningful use program. Despite these frustrations, widespread interoperability has not been realized and we have observed varying degrees of willingness by vendors to utilize open standards to facilitate interoperability.

In recommending standards and specifications for inclusion in the 2016 Interoperability Advisory, ONC should consider the following overarching principles:

- ONC should give preference and promote the use of interoperability standards and specifications that will not result in additional costs being imposed on end-users of health IT. Similarly, ONC should favor standards and specifications that are free and have minimal licensing obligations.
- We are encouraged by and applaud the development of the Fast Healthcare Interoperability Resources (FHIR) as an additional pathway toward enabling the widespread exchange of electronic health information.
- We are supportive of standards that are non-proprietary to help in ameliorating the emerging issue of information blocking.

Our comments as they relate to the content of the 2016 Interoperability Standards Advisory are included below:

II-B: Care Plan: ONC should promote cancer specific care planning standards and specifications including the *HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary* to promote the exchange of cancer specific care planning information.

Care planning is an essential component of high-quality cancer treatment and is critical to increasing the quality and value of cancer care. Multiple specialists often treat patients with cancer with their primary oncologist taking responsibility for the careful coordination of their treatment. ONC should promote cancer specific care planning standards and specifications in addition to the *HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition*.

ASCO has actively worked with other stakeholders to develop the *HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary (COTPS)*.[1] This specification is the first interoperability specification that is focused on treatment planning and summarization of care for patients with cancer. Currently, the specification is used to coordinate care among providers caring for patients with curable breast and colon cancer. This standard is also useful for communicating the treatment summary and potential long-term side effects to the patient, their caregivers, the patient's primary care provider and other involved providers upon completion of chemotherapy.

ASCO is also working to update the COTPS specification to add the ASCO Survivorship Care Plan (SCP) template. This version is expected to be released in the spring of 2016. SCPs are required by a number of accreditation bodies including the Commission on Cancer. Facilitating the implementation of the COTPS specification will improve cancer care and aid in enabling the exchange of cancer specific care information.

The COTPS should be added to the 2016 Interoperability Advisory; use cases include Care Plan, Treatment Summarization, Care Collaboration, Transitions in Care, and Cancer Care.

The inclusion of specific interoperability standards related to care planning for cancer is in the best interest of patients, providers, and the Federal government. Robust interoperability standards that increase coordination and reduce the potential for duplicative tests or costly interventions as a result of insufficient clinical information are especially important in cancer treatment given its cost and complexity. ONC should promote specific standards for cancer treatment to fully leverage the exchange of information to improve the quality of cancer care and patient safety.

II-E Electronic Prescribing: ONC should promote standards that do not encourage vendors to pass along costs to the end user. Basic health IT functions like e-prescribing should not require the use of standards or specifications that are likely to be passed on to end users.

Oncologists rely on electronic prescribing each day to order and prescribe adjuvant and palliative treatments to their patients, including controlled substances to relieve pain and suffering. We are pleased that there has been widespread adaption of the "NCPDP SCRIPT Standard, Implementation Guide, Version 10.6" for creating a new prescriptions and transferring them to a pharmacy. However, we remain concerned that the costs for developing and implementing the listed standards for cancellation of a prescription, pharmacy notification to the prescriber of fill status, and a prescriber's ability to obtain a patient's medication history will be passed on to our membership in the form of higher licensing or vendor fees for end-users. Although we understand that the NCPDP standard is well recognized and has been widely adopted for certain functions, we continue to believe that ONC should focus on promoting standards that are free so that they do not produce significant financial burdens for end-users.

II-F: Family health history (clinical genomics): ONC should continue to include *HL7 Version 3 Standard: Clinical Genomics Pedigree* in the Interoperability Standards Advisory and take steps to address the urgent need to keep pace with new clinical knowledge by developing computable cancer staging and genomic data ontology.

The future of cancer care will be shaped in large part by the development of personalized medicine, which allows oncologists to make decisions that are based on a patient's specific genetic makeup and their cancer's molecular profile. In the area of cancer, much of the conversation about

[1] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=327

personalized medicine has focused on a clinician's ability to target therapeutic regimens to an individual patient based on specific somatic gene mutation(s). Initial steps are needed to build interoperability in this space to ensure that health care providers are able to exchange genomic information in a comprehensive and accurate manner.

ASCO supports the inclusion of the *HL7 Version 3 Standard: Clinical Genomics: Pedigree* in the 2016 Interoperability Standards Advisory. This standard provides value for oncologists and other medical specialists that rely on advanced family history and genomic information to make treatment decisions. In addition to this standard it will be necessary for ONC to emphasize the importance of developing the appropriate vocabulary to capture a family's genomic health history and communicate other important genetic information such as specific genetic mutations between systems. These steps will enable health IT systems to keep pace with the advance of personalized medicine.

Given the clinical potential of personalized medicine to affect not only cancer care but many other specialties, significant resources should be devoted by industry to increasing the functionality of EHRs and other health IT within this space. Specifically, there is an urgent need for the development of computable format standards (i.e., ready conversion from paper-based to digital format) for a genomic data ontology with a flexible hierarchy that will allow health IT systems to keep pace with new clinical knowledge. As new interoperability standards and specifications are developed to communicate genomic information, ONC should continue to promote those that are openly available standards or specifications.

We are encouraged by the work of the HL7 Clinical Genomics work group, which is actively promoting the addition of genomic specifications to the FHIR standard. If FHIR implementation in the future is widespread, it is imperative that genomic data standards be well represented. These are not considered to be within the "80% rule" scope of the central FHIR Resources so will need to be instantiated as well-supported Profiles. This work should be strongly supported by the ONC so that cancer patients can have the expectation that their genomic and family history data will be accurately and easily exchanged thru the FHIR mechanism.

II-K: Public Health Reporting: ONC should support state and local public health authorities to develop the appropriate resources to receive cancer case reports from providers and institutions.

ASCO supports the inclusion of the *HL7: CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries for Ambulatory Healthcare Providers*. But despite relatively widespread adoption of health IT, our membership still reports significant difficulties in accurately transmitting information to public health agencies through this mechanism. This is due to at least in part to lack of funding for public health agencies to upgrade their information technology to the point where it is able to receive information on cancer cases transmitted using CDA-based standards by providers and institutions. We have heard from our membership that the barriers to implementing this particular CDA have been onerous, and in fact have only heard of one successful transmission, in the state of Kentucky. This was the result of close collaboration with the Kentucky Cancer Registry, yet the transmission was unable to be maintained for more than a period of several months. This disappointing track record suggests that vendors may need additional inducements or mandates to implement CDA standards with complex data element requirements.

We encourage state agencies and the ONC to take the steps necessary to ensure that state and local public health agencies have the necessary resources to ensure that meaningful interoperability is

achieved in cancer case reporting. Failure on the part of public health agencies to receive cancer case information creates counterproductive regulatory burdens on end-users of health IT. We also urge ONC to take leadership in developing data transportation methods for cancer case reporting that are standardized across all jurisdictions to further alleviate barriers in reporting cancer cases to state and local public health agencies.

II-L: Quality Reporting: ONC should explore standards that go beyond HL7 Quality Reporting Document Architecture (QRDA) for quality reporting activities. The increased role of quality reporting in reimbursement systems, including the Medicare program, demands the use of non-proprietary standards that are capable of capturing the relevant clinical information.

ONC should explore additional standards for quality reporting that go beyond the current HL7 Quality Reporting Document Architecture (QRDA). The efficient exchange of quality data will be imperative for helping providers meet reporting obligations under the Physician Quality Reporting System (PQRS) and new standards created through the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

In studying new standards for inclusion in the Interoperability Standards Advisory, ONC should focus on embracing standards for quality reporting that do not rely on proprietary interfaces and data calls for quality reporting to ensure that patients are able to access the full benefits of quality improvement activities.

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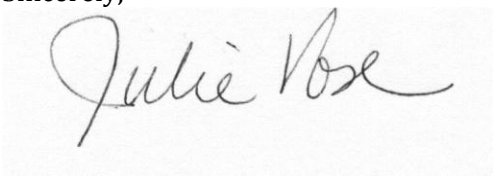
Thank you for the opportunity to provide comments on the 2016 Interoperability Standards Advisory. Should you have any questions please do not hesitate to contact Shelagh Foster at Shelagh.Foster@asco.org.

Sincerely,



Julie M. Vose, MD, MBA, FASCO
ASCO President